

**REMARKS**

In an Official Action dated March 26, 2004 the Examiner objected to claims 5-7, 9, 12, 17, 21, 27, 55, 56, 58 and 59, and rejected claims 1-4, 8, 10, 11, 13-16, 18-20, 22-26, 28-32, 54, 57 and 60 over a variety of prior art references. Applicants request that the Examiner reconsider the rejection. In addition, Applicants request that the Examiner favorably consider newly presented claims 61-89.

**Botich et al 6,039,713**

Claims 1 and 54 and dependent claims 2,13,15,16,57 and 60 were rejected under §102 over 6,039,813. With respect to claim 1, Botich does not teach a medical device comprising a barrel, a vial holder displaceable within the barrel having a socket configured to receive the vial, a needle and a transfer chamber for receiving medicinal fluid from the vial. Accordingly, claim 1 is patentably distinct from Botich. Dependent claims 2, 13, 15 and 16 are even further patentably distinct from Botich.

With respect to claim 54, Botich does not teach a device having a housing, a socket for receiving a container of medicinal fluid, a pressurizing element, and a chamber for receiving substantially all of the medicinal fluid. In Botich, a tube extends between a rear needle that projects into a cartridge and an injection needle. The tube operates as a conduit. If the tube were sized to accommodate substantially all of the medicinal fluid, it would not be possible to expel the fluid from the tube. In other words it would not be possible to provide an injection, which is the entire purpose of Botich. Accordingly, Botich does not teach or suggest the features of claim 54. Therefore, Applicants request that the Examiner reconsider the rejection of claim 54 and dependent claims 57 and 60.

**Knauer 6,607,508**

The Examiner rejected claims 1 and 19, along with dependent claims 2-4, 8, 11, 13-15, 20, 22, 24-28, 30 and 31 as anticipated by Knauer 6,607,508. However, Knauer

is directed to an injection device useable with a "standard needle system". Knauer is not directed to a safety medical device that prevents inadvertent needle sticks.

Therefore, Knauer differs from Applicants' claimed device, as discussed below.

With respect to claim 1, Knauer does not teach a medical device comprising a barrel, a vial holder displaceable within the barrel having a socket configured to receive the vial, a needle and a transfer chamber for receiving medicinal fluid from the vial. Accordingly, claim 1 is patentably distinct from Knauer. Dependent claims 2-4,8,11 and 13-15 are even further patentably distinct from Knauer.

With respect to claim 19, Knauer does not teach or suggest a medical device comprising a holder configured to receive a vial, a retractable needle, a biasing element biasing the needle rearwardly, and a needle retainer releasably retaining the needle in the extended position. Accordingly, claim 19 is patentably distinct from Knauer. Dependent claims 20, 22, 24-28, 30 and 31 are even further patentably distinct from Knauer.

**Lavi et al. 6,364,865**

The Examiner rejected claims 1 and 19, along with dependent claims 2-3, 8, 10, 11, 13, 15, 18-20, 22-26, 28-30 and 32 as anticipated by Lavi et al 6,364,856. However, Lavi is directed to a complicated drug mixing a delivery system, not a safety medical device that prevents inadvertent needle sticks. Therefore, Lavi differs from Applicants' claimed device, as discussed below.

With respect to claim 1, Lavi does not teach a medical device comprising a barrel, a vial holder displaceable within the barrel having a socket configured to receive the vial, a needle and a transfer chamber for receiving medicinal fluid from the vial. Accordingly, claim 1 is patentably distinct from Lavi. Dependent claims 2-3, 8, 10, 11, 13, 15 and 18 are even further patentably distinct from Lavi.

With respect to claim 19, Lavi does not teach or suggest a medical device comprising a holder configured to receive a vial, a retractable needle, a biasing element biasing the needle rearwardly, and a needle retainer releasably retaining the needle in the extended position. Accordingly, claim 19 is patentably distinct from Lavi. Dependent claims 20, 22-26, 28-30 and 32 are even further patentably distinct from Lavi.

### **Newly Presented Claims 61-89**

Newly presented claims 61-89 are also patentably distinct from the prior art of record. For instance, none of the prior art of record teach or suggest the features recited in claim 61, which include a medical device having a barrel, a retractable needle, a biasing element, a retainer releasably retaining the needle, and a transfer chamber, wherein the needle is automatically released for retraction at the end of an injection. Accordingly, Applicants request that the Examiner favorably consider newly presented claim 61 along with dependent claims 62-79

With respect to claim 80, none of the prior art teaches or suggests a medical device cooperable with a retractable needle assembly, comprising a housing cooperable with the needle assembly, a socket for receiving the vial, a piston for pressurizing the vial, a chamber for receiving medicinal fluid, and a operable to expel the fluid from the chamber, wherein the housing has an activation surface cooperable with the needle assembly that is adapted to activate retraction of the needle after use. Accordingly, Applicants request that the Examiner favorably consider newly presented claim 80 along with dependent claims 81-89.


In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.



Patent Application No. 10/099,864

Respectfully submitted,

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

I hereby certify that this Response and accompanying papers are being deposited on July 28, 2004 with the United States Postal Service as first-class mail in an envelope properly addressed to Commissioner for Patents, Alexandria, VA 22313-1450.

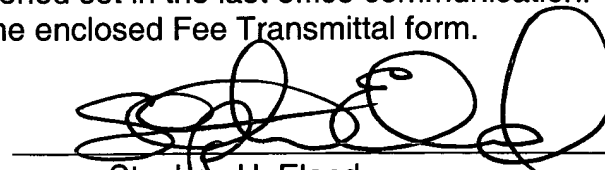
July 28, 2004  
Date of Certificate

  
Christine Edinger

**Petition for Extension Under 37 CFR §1.136(a)**

Applicant's undersigned Attorney hereby petitions for an extension of time of TWO months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

July 28, 2004  
Date of Certificate

  
Stephen H. Eland  
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